GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2492
ANSWERED ON:15.12.2004
AUTHORITY EXERCISABLE BY DRUG CONTROLLER OF INDIA
Gandhi Smt. Maneka

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) Whether the Drug Controller of India is not empowered with functional autonomy being subordinate to the Ministry;

(b) if so, the details of authority exercisable by the Drug Controller alongwith details of amendments made in this regard during the last three years ; and

(c) the action taken to make the post of Drug Controller an independent one by the Government ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) Central Drugs Standards Control Organization (CDSCO), which is headed by Drugs Controller (India), redesignated as Drugs Controller General (India), is a subordinate office of Directorate General of Health Services under Ministry of Health & Family Welfare.

(b) & (c) The functions of CDSCO are multifarious in nature under which Drugs Controller (India) exercises its authority in respect of

A Approval of market authorization/import of new drugs and clinical trials.

B To approve licenses to manufacture certain categories of drugs as Central Licensing Approving Authority (CLAA) i.e., blood banks and blood products, large volume parenterals, sera and vaccines and rDNA-based products (biotech drugs).

C Approval of registration of overseas manufacturers and their products (both bulk and formulations).

In addition, the other functions undertaken by CDSCO headed by Drugs Controller (India) are:

i) Screening of drugs for prohibition of drugs which are harmful or irrational in nature under Drugs and Cosmetics Act and Rules thereunder.
ii) Work relating to Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC).
iii) Supervision of functioning of Central Drugs Testing Laboratories.
iv) Publication of Indian Pharmacopoeia.
v) Implementation of National Pharmacovigilance Program.
vi) Guidance to pharmaceutical industry and other stakeholders.
vii) Coordinating the activities of State Drugs Control Organizations to achieve uniform administration of Drugs and Cosmetics Act & Rules and policy guidance.
viii) Participating in the WHO- GMP certification scheme.
ix) Conducting training programmes for Drugs Inspectors and Govt, analysts etc.
x) Narcotic drug quota distribution for medicinal products.
xi) Evaluation/screening of applications for granting No Objection Certificate for export, of unapproved/banned drugs.
xii) Miscellaneous.

There is no proposal at present to make the post of Drug Controller an independent one.